INSTRUMENTARIUM

K063773
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510(k) Summary

Date

December 15, 2006

JAN 3 1 2007

Manufacturer

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United States Sales Representative (U.S. Designated agent)

INSTRUMENTARIUM DENTAL INC.
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Contact Person: Mr. Frank Kashinski, Tel +1 414 747 6315

Trade name:

Volumetric Tomography

Common name:

Film/digital dental panoramic X-ray equipment with cephalostat.

Classification name:

Extraoral source X-ray system (21 CFR 872.1800, product code EHD)

Description:

The Volumetric Tomography imaging option for Orthopantomograph® OP100 and OP200 product families utilizes Statistical Inversion (SI) that is used to reconstruct tomographic images from a set of pre-acquired projection radiographic images of the object. To reconstruct means producing cross-sectional images from a set of projection images by using computer calculation. Projection image means a radiographic image from a certain angle in which the structures of the object are seen superimposed. Tomographic means viewing an object as a series of thin slices.

Projection images are captured with a digital panoramic unit using scanning as the imaging method. Scanning projection images is previously known technique and commonly used for example in digital cephalometric units. Along with the object a set of fiducials are recorded on the projection images to be used for geometry refinement and cross-registration between the reconstructed image set and a separate panoramic scout image.

Tomographic images are then reconstructed from the projection images with a computer. For dimensional information for dental implant planning and information about location of impacted teeth all three imaging modalities can be used: projection image set, the panoramic image and the reconstructed image set. The tomographic slice and the slice angle are selectable after reconstruction to ensure the correct positioning of the slice referenced to the anatomy. In addition to the selection of the tomographic slice also the slice angle is user adjustable to ensure the correct position and angle compared to the anatomy.

When comparing this method to previously known tomographic techniques like continuous linear tomography (such as the OrthoTrans option for OP100 and OP200 film units), the Volumetric Tomography imaging concept can be thought as a discrete tomography in which several slices can be produced from a set of projection images.

The calculation algorithm – Statistical Inversion – is more thoroughly described in the following scientific publications:

Statistical inversion for medical x-ray tomography with few radiographs: I. General theory; Phys. Med. Biol. **48** (2003) 1437–1463 PII: S0031-9155(03)57800-9

Statistical inversion for medical x-ray tomography with few radiographs: II. Application to dental radiology; Phys. Med. Biol. **48** (2003) 1465–1490 PII: S0031-9155(03)57801-0

The Volumetric Tomography option comes with a complete image handling software, CliniView, offering the same familiar and intuitive user interface as with the conventional modalities (i.e. Panoramic, cephalometric and intraoral radiographic images). In addition to the Volumetric Tomography specific functionality CliniView features include dynamic zooming, brightness and contrast adjustments, edge enhancement, and measurements. The software runs on Windows 2000 and XP operating systems.

Intended use:

Volumetric Tomography is intended to be used for producing cross-sectional (tomographic) radiographic images from the edentulous or dentate area of the jaws. The cross-sectional images provide dimensional information for dental implant planning and information about location of impacted teeth.

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Substantial Equivalence:

We consider Volumetric Tomography is similar in design, composition and function to the following predicate device introduced into commercial distribution after May 28, 1976:

Orthopantomograph® OP100/Orthoceph® OC100 with OrthoTrans linear tomography option #K973642.

The comparison of characteristics supports substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2007

Instrumentarium Dental, PaloDEx Group OY
% Mr. Frank Kashinski
Official Correspondent
Instrumentarium Dental, Inc.
300 West Edgerton Ave.
MILWAUKEE WI 53207-6025

Re: K063773
Trade/Device Name: Volumetric Tomography
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH and OAS
Dated: December 15, 2006
Received: December 21, 2006

Dear Mr. Kashinski:

This letter corrects our substantially equivalent letter of January 31, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063773

Device Name: Volumetric Tomography

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Volumetric Tomography is intended to be used for producing cross-sectional (tomographic) radiographic images from the edentulous or dentate area of the jaws. The cross-sectional images provide dimensional information for dental implant planning and information about location of impacted teeth.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063773